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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,873	10/05/2001	John P. McKearn	CU-2559 RJS	2817

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Mr. James M. Waner
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EXAMINER	
HARTLEY, MICHAEL G	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/857,873	MCKEARN ET AL.	
	Examiner	Art Unit	
	Michael G. Hartley	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2003 and 21 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,42-45,89,90 and 102-121* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,42-45,89,90 and 102-121* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Amendment

The amendment filed 11/7/2003 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 42, 43, 90, 104, 106, 108, 110, 112, 114, 116, 118 and 119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reddy et al reference taken with Takahiko et al. reference, for the reasons set forth in the office action mailed 8/7/2003.

Claims 44, 45, 89, 90, 102 103, 105, 107, 109, 111, 113, 115, 117, 120 and 121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reddy et al reference taken with Takahiko et al. reference taken with the Aleman et al reference, for the reasons set forth in the office action mailed 8/7/2003.

Response to Arguments

Applicant's arguments filed 11/7/2003 and 1/21/2004 (supplemental) have been fully considered but they are not persuasive.

Applicant asserts that Reddy and Takahiko provide no basis to conclude that compositions for the same use, i.e., gencitabine and celecoxib, may be used in combination therapy.

This is not found persuasive because both references teach the use of chemotherapeutic agents for treating the same cancer, i.e., colorectal cancer. The art of chemotherapeutics most often employs combinations or cocktails of such anticancer agents to provide a chemotherapy. Since one of ordinary skill in the art of chemotherapy would recognize that combination therapies are more the norm than the exception, and when performing endeavors in the area of chemotherapy for particular cancers (e.g., colorectal) would look at chemotherapeutics having the ability to treat the same cancer, thus, would be motivated to combine such related treatments to provide a more comprehensive treatment regimen. The

examiner relied on In re Sussman. The cite is: In re Sussman, 136 F.2d 715, 30 C.C.P.A., Patents, 1107, 1943 C.D. 518 [58 USPQ 262]; however, a copy of this entire cite was not obtainable at this time. This was relied for the holding that it is not invention to combine old ingredients of known properties where the result possesses no more than the additive effect of the ingredients. Also see, Ex parte Walker, 1923 C.D. 39; In re Trattner, 30 F.2d 879, 1929 C.D. 158. This is especially true in the field of chemotherapy wherein combination therapies of known ingredients having known same therapeutic effects for treating cancer is common place. This is supported by applicant's own disclosure, for example, see page 4 of the specification and the various combination chemotherapies disclosed in the prior art cited on page 4.

Applicant asserts that Aleman fails to teach or suggest the use of either celecoxib or gemcitabine and radiation.

While this is true, the Aleman reference was relied on for its teaching that it is known in the art to combine radiation with chemotherapy to gain an additive effect for the treatment of colorectal cancer. The combination of chemotherapeutics as claimed was discussed above. Clearly, Aleman provides a teaching that radiation should be combined with various chemotherapeutic regimens to gain the benefit of an additive affect in treating colorectal cancer.

Applicant also asserts that the Crane reference shows unexpected results of an additive effect when celecoxib and gemcitabine were combined for the treatment of pancreas cancer.

This results have been reviewed but are not persuasive to obviate the rejections over the pending claims because no claims are commensurate in scope with the cited results. The results are specific to pancreatic cancer and due to the diversity of cancers, the unpredictability of treating various different cancers and the unknown causes and origination of cancers, this showing in not commensurate in scope to show that this trend would hold true of treating any neoplasia, let alone, preventing any neoplasia.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 44, 102, 103 and 118-121 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific neoplasia disorders disclosed, does not reasonably provide enablement for the term "neoplasia disorder". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims, for the reasons set forth in the office action mailed 8/7/2003.

Response to Arguments

Applicant's arguments filed 11/7/2003 and 1/21/2004 (supplemental) have been fully considered but they are not persuasive.

Applicant asserts that the specification provides the chemical structure of celecoxib, how to make it, the chemical structure of gemcitabine, how to make it, and how to administer the combination for the treatment of neoplasia.

First, the rejection was not based on "how to make" but rather was based on "how to use" or performing the methods of "treating or preventing a neoplasia condition." The term "neoplasia disorder" would encompass so many diverse cancerous conditions that the skilled artisan would not be treat all these such diverse and different conditions encompassed thereby without undue experimentation. Given the diversity of how different cancers respond to treatment it would require undue experimentation to treat various conditions encompassed by neoplastic disorders except for the specific cancers shown in the specification. This is because it would require undue experimentation to determine what dosages may be used for each different neoplastic condition, what type of administration means, length of treatment regimen, acceptable toxicity levels, etc. The specification does not provide the requisite guidance to perform a treatment or prevention of all neoplasia since all these critical components are not specifically provided for in the specification. This is further complexed by the fact that the claims are drawn to "treating or preventing" and the predictability in the art in preventing cancer is very low, given ambiguity in the causes of various cancers. Clearly, one of ordinary skill in the art would face undue experimentation to determine the risks of the various dosages and treatment regimens needed for <u>preventing</u> any

neoplasia disorders with the risks of toxicity of the combined agents, as well as, with radiation. The use of radiation for the prevention of cancer is not well understood in the art due to the inherent risks of radiation to the human body.

Conclusion

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (571) 272-0616. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael G. Hartley
Primary Examiner
Art Unit 1616

5/17/2004